STATE OF MICHIGAN
DEPARTMENT OF
ENVIRONMENT, GREAT LAKES, AND ENERGY
LANSING

GRETCHEN WHITMER
GOVERNOR

LIESL EICHLER CLARK
DIRECTOR

August 4, 2022

VIA E-MAIL and U.S. MAIL

Mr. Jim Saric
Remedial Project Manager
United States Environmental Protection Agency
Region 5
77 West Jackson Boulevard (SR-6J)
Chicago, Illinois 60604-3511

Dear Jim Saric:

SUBJECT: Michigan Department of Environment, Great Lakes, and Energy (EGLE) Comments on the Draft Supplemental Remedial Investigation (SRI) Report, Revision 1, dated September 30, 2021, Area 5 of Operable Unit 5 (OU5), Allied Paper Inc./Portage Creek/Kalamazoo River Superfund Site (Site).

By way of this correspondence, EGLE formally submits this cover letter and detailed comments (attached) for inclusion in the Administrative Record for the Site.

Enclosed are EGLE's detailed comments on the draft subject Area 5 SRI Report. EGLE's comments were developed after reviewing the subject report, presentation slides from Area 5 technical work group meetings, comments provided on the Draft SRI Report and responses to those comments provided by Georgia-Pacific (GP).

GP is the sole remaining Respondent to an Administrative Settlement Agreement and Order on Consent (AOC) for Remedial Investigation/Feasibility Study (RI/FS) (Docket No. V-W-07-C-864) dated February 2007, which requires the completion of an SRI and Feasibility Study (FS) and submittal of SRI and FS Reports for OU5. The Area 5 Draft SRI Report, Revision 1, was provided electronically on September 30, 2021, and in accordance with Paragraph 33 of the AOC for RI/FS.

EGLE's detailed comments on the subject SRI Report are provided as an enclosure to this cover letter and a few key comments are included below.

1. Section 4.1.2.3 states that "reoccupied data are from SRI [Monitored Natural Recovery] MNR [lines of evidence] LOE sediment sampling locations that were sampled within about 15 ft of a pre-SRI sampling location." EGLE notes that comparing subaqueous sediment polychlorinated biphenyl (PCB) concentrations on a point-by-point approach to assess the efficacy of MNR is a flawed approach. This site has a demonstrated history of small-scale heterogeneities in PCB concentration, and the ability to directly reoccupy a previous subaqueous sediment core location is near impossible (e.g., boat

positioning, global positioning system [GPS] accuracy, issues with sampling from the water's surface through the water column, etc.).

Any evaluation of temporal trends in total PCB concentrations (utilizing accurate PCB concentration data) should be conducted on an areal basis. This areal extent could be via lake bottom feature, sediment decision management unit (SDU), etc. A point-by-point comparison should not be performed. Furthermore, multiple samples within a single SDU should be used for compositing and to establish that area's "concentration".

2. Prior to completion of the Phase 2 SRI sampling in Area 5, the Respondents implementing the Area 1 remedial design and remedial action (GP, International Paper, and Weyerhaeuser) had been made aware of a potential low bias in total PCB (TPCB) measurements reported by the laboratory when analyzing samples for TPCBs as Aroclors ($TPCB_{AROCLORS}$) using Method 8082 (M8082). This low bias in M8082 $TPCB_{AROCLORS}$ measurements at the Respondents laboratory (Pace) was originally identified by EGLE in 2018 following the collection of split floodplain samples during the remedial design pre-design investigation in the Plainwell Impoundment.

   In October 2019, a follow-up sampling event was completed in Area 4 by GP and the United States Environmental Protection Agency (US EPA) to evaluate the low bias in $TPCB_{AROCLOR}$ measurements, and EGLE was also able to collect split samples during that event as a condition of a land use permit issued by the Michigan Department of Natural Resources.

   EGLE completed and submitted several statistical analyses on the split floodplain soils samples collected from the Plainwell Impoundment. The US EPA completed statistical analyses using the 2019 Trowbridge data. EGLE's statistical evaluations of the Area 1 split sample data examined data from all locations and across all reported TPCB concentration ranges. The US EPA statistical evaluation eliminated and did not consider data with reported TPCB concentrations that were less than 1 part-per-million (ppm) and instead honed-in on those samples with reported TPCB concentrations at or near remedial goals that apply to soils (i.e., 2.5, 5, 11, 20,23, and 50 ppm).

   Despite concerns raised by EGLE and the ongoing effort by the technical work group to evaluate the low bias in TPCB measurements, GP elected to continue to undertake work across several Areas of OU5 and submit samples to their analytical laboratory (Pace) for analysis under the existing M8082 standard operating procedure (SOP).This included the collection of soil and sediment samples by GP from Area 5 as part of the ongoing SRI and analysis of those samples by their laboratory using their existing M8082 SOP which had recently been shown to produce inaccurate measurements of TPCBs.

   As the bias was discovered, the project team sought to compare and standardize laboratory SOPs for all laboratories at the Site using M8082 to measure $TPCB_{AROCLORS}$. This included numerous meetings with several Responsible Parties (RPs) (i.e., GP, International Paper, and National Cash

Register Corporation), their respective laboratories (i.e., Pace and Eurofins), and the US EPA On Scene Coordinator and their laboratory (ALS), since these Parties are all currently completing work at OU5 and their respective laboratories are analyzing samples for $TPCB_{AROCLORS}$ using M8082.

Since the SRI sampling in Area 5 was completed, all laboratories using M8082 to measure $TPCB_{AROCLORS}$ including the laboratory that analyzed the SRI samples in Area 5 have implemented several rounds of corrective actions to attempt to address this low bias. However, the preliminary statistical evaluations that identified a low bias in $TPCB_{AROCLORS}$ measurements and the laboratory corrective actions that followed did not focus on other sample matrices (i.e., sediments) that are analyzed for $TPCB_{AROLCORS}$ using M8082 or evaluate the degree of bias at or near sediment action levels (i.e., 0.33 ppm and 1 ppm TPCB) which are one to two orders of magnitude lower than action levels for soil. EGLE deemed it necessary to continue to evaluate the quality of sediment data generated by all laboratories following standardization of their M8082 SOP for $TPCB_{AROCLORS}$. To do this, EGLE implemented a split sample program during sediment confirmation sampling at Crown Vantage Side Channel and submitted split samples to Vista Analytical Laboratory for analysis using Method 1668C (M1668) to analyze sediment samples for TPCB by congeners ($TPCB_{CONGENERS}$).

The comparison of EGLE's $TPCB_{CONGENERS}$ measurements using M1668 to the Total $PCB_{AROCLORS}$ measurements produced by the Respondents analytical laboratory using M8082 shows that the $TPCB_{AROCLORS}$ measurements are still biased low, even in samples with fairly high TPCB results, with 17 of the 21 pairs having a $TPCB_{CONGENERS}$ measurement greater than the $TPCB_{AROCLORS}$ measurement.

Given that the risk and regulatory thresholds at the Site are based on TPCBs, accurate and precise measurements of TPCBs in all media and across time and space is paramount to the implementation of a protective and effective remedy. Since the Area 5 SRI was completed prior to the laboratory implementing corrective actions to improve data quality, a significant low bias in $TPCB_{AROCLOR}$ measurements that are presented in the subject SRI Report likely exists. If TPCB measurements are inaccurate and biased low the nature and extent of contamination and perceived risks in Area 5 may be underrepresented, remedial footprints will be artificially reduced, design and cost estimates for remedies will be incomplete and inaccurate, and remedies that are implemented will not achieve their anticipated level of risk reduction. This issue directly impacts EGLE's ability to support conclusions presented in the SRI Report, the Alternatives developed during the Feasibility Study (FS) based on those conclusions, and the selection of an FS Alternative as a proposed remedy.

EGLE continues to advocate for the use of sound, reliable analytical methods to measure TPCBs; the collection and analysis of samples for all constituents of concern (COCs) including TPCBs and select PCB, dioxin, and furan congeners

summed as a total toxic equivalency quotient (Total TEQ), and the presentation of TPCBs as Aroclor, homolog, and congener equivalents.

This approach is consistent with language contained in US EPA guidance on the benefits and application of congener analysis which was recently updated in September 2021.

3. The first full paragraph in Section 6.2 states that Site-wide preliminary remediation goals (PRGs) for Area 5 were based on the Area 4 Terrestrial Baseline Ecological Risk Assessment (TBERA) (11 milligrams-per-kilogram [mg/kg] TPCBs; 1,000 nanograms-per-kilogram [ng/kg] mammalian total TEQ; 7,000 ng/kg avian total TEQ), and, "Therefore, a formal TBERA quantitatively assessing risk is not warranted for Area 5." The paragraph goes on to state that this was discussed in an April 23, 2020 Work Group meeting with the US EPA, EGLE, GP, and consultants. EGLE has significant concerns with the Area 4 TBERA, that have been laid out in great detail to the US EPA and the Respondents in writing, calls, and meetings. EGLE's technical concerns with the Area 4 TBERA show that the PRGs selected for PCBs and dioxins were not scientifically defensible and will not be protective. All those comments are now applied to the Area 5 TBERA. Additional information previously provided by EGLE on the Area 4 TBERA are included as Attachment 1.

4. Section 4.3.5. states that the pending avian PRG for Total TEQ is 7,000 ng/kg. EGLE has previously noted concerns regarding the Total TEQ PRG for avian ecological receptors of 7,000 ng/kg, since the avian toxicity reference values (TRVs) (NOAEL=14 ng TEQ/kg/day and LOAEL=140 ng TEQ/kg/day) derived from Nosek et al. (1992) are acute lethality values.

   Section 5.2.2 of the November 16, 2018 TBERA (Appendix L of the Area 4 SRI) states, "Mortality was observed in birds exposed at a concentration of 140 ng/kg/day, with 57 percent of the birds in this group dying between weeks 15 and 24…Greater than 98 percent embryo mortality was observed in eggs laid by hens exposed at a concentration of 140 ng/kg/day. Based on the observed mortality, reduced egg production, and lower embryo survival at an exposure dose of 140 ng/kg/day, a LOAEL TRV of 140 ng/kg/day and a NOAEL of 14 ng/kg/day were identified from this study." Consequently, a cleanup based on the LOAEL value will potentially result in mortality of half of the resident invertivorous birds, and nearly complete mortality of their eggs. Substituting NOAELs for LOAELs in the US EPA's method, EGLE estimates the protective avian PRG in this scenario to be 375 ng/kg Total TEQ.

   EGLE strongly encourages the US EPA to reassess the pending avian PRG for Total TEQ.

5. The first full paragraph in Section 6.2 states that Site-wide PRGs for Area 5 were based on the Area 4 TBERA (11 mg/kg TPCBs; 1,000 ng/kg mammalian TEQ; 7,000 ng/kg avian TEQ), and, "Therefore, a formal TBERA quantitatively assessing risk is not warranted for Area 5."

EGLE has significant concerns with the Area 4 TBERA, that have been laid out in great detail to the US EPA, GP, and Wood in writing, calls, and meetings. EGLE's technical concerns with the Area 4 TBERA show that the PRGs selected for PCBs and dioxins were not scientifically defensible and will not be protective. All those comments are now applied to the Area 5 TBERA. Additional information previously provided by EGLE on the Area 4 TBERA are included as Attachment 1.

6. EGLE requests transmittal of the Area 5 hydrodynamic model setup and input files necessary for running the various steady-state flow conditions described in the SRI report (typical normal flow, bankfull flow, 2-year return flow, 16-year flow, and 100-year flow), as well as a set of output files for any one of these flow conditions for benchmarking purposes. EGLE sees value in reviewing draft files so that the project can reach consensus on a path forward if errors/discrepancies are found during its review rather than after a document has been finalized. An updated hydrodynamic model with a dam-out scenario should be included to evaluate potential risks under a dam-out scenario.

7. The Alternatives Screening Technical Memorandum and FS should incorporate a dam-out scenario and at a minimum account for potential changes in floodplain boundaries (e.g., previously inundated sediment that will become future floodplain), flooding (e.g., extent of flooding under 2-year and 100-year flows) and associated exposure risks (e.g., residential/recreational use in previously inundated areas).

8. In Section 4.1.1., PCB concentrations at the 26th Street bridge (Trowbridge outlet) and M89 Bridge (Lake Allegan inlet) show similar trends with the various independent variables, but there is an apparent increase in PCB concentrations from the Trowbridge outlet to the Lake Allegan inlet. Although not over same spatial extent as the long-term monitoring data, mean and median values measured during the HyST/OPTICS program in 2019 (values in Table 4-14) also show a similar trend - increasing PCB concentrations from Station 1 to Station 2. Revise the text to mention this spatial trend and potential insights into fate and transport processes from this trend.

EGLE appreciates the opportunity to review and comment on the subject SRI Report for Area 5 and looks forward to working with all parties involved on this project. If you have any questions, please contact Mr. Daniel Peabody, Environmental Quality Analyst, Remediation and Redevelopment Division at 517-285-3924; PeabodyD@Michigan.gov; or EGLE, P.O, Box 30426, Lansing, Michigan 48909-7926

Sincerely,

Daniel Peabody
Environmental Quality Analyst
Superfund Section
Remediation and Redevelopment Division

Att/cc:
Sarah Rolfes, US EPA
Megen Miller, Michigan Department of Attorney General
Matt Diana, Michigan Department of Natural Resources (MDNR)
Jay Wesley, MDNR
Mark Mills, MDNR
Kyle Alexander, EGLE
Luke Trumble, EGLE
Keegan Roberts, CDM Smith
David Kline, EGLE
Joseph Walczak, EGLE
Lisa Williams, US Fish and Wildlife Service

GENERAL COMMENTS

Commenting Organization: EGLE
General Comment #1: EGLE requests transmittal of the Area 5 hydrodynamic model setup and input files necessary for running the various steady-state flow conditions described in the SRI report (typical normal flow, bankful flow, 2-year return flow, 16-year flow, and 100-year flow), as well as a set of output files for any one of these flow conditions for benchmarking purposes. EGLE sees value in reviewing draft files so that the project can reach consensus on a path forward if errors/discrepancies are found during its review rather than after a document has been finalized.

Commenting Organization: EGLE
General Comment #2: The hydrodynamic model documented in Appendix Q was developed with the objective of calculating water levels, velocities, and bed shear stresses under a range of flow conditions. However, the model was calibrated under (1) a limited flow condition (a single average flow condition), (2) to limited data (an instantaneous longitudinal profile of water levels), and (3) to limited metrics (only water level). Therefore, model performance for conditions outside of average flow (mainly high flow conditions which are relevant for the sediment stability assessment) and for metrics beyond water level (mainly velocities which are relevant for bed shear stresses and the sediment stability assessment) is untested. In other words, model performance for the metrics and conditions of interest to the sediment stability assessment cannot be considered reliable. In order to support its use in the sediment stability assessment, model performance should be assessed over a range of flow conditions and to additional metrics. Data collected as part of the Area 5 investigations can be used to calibrate and extend the applicability of the model. The additional data for use in extending the model calibration include:
- Water level time-series data at three stations in Area 5 over 2017-2019
- Water level and velocity profile time-series data at two stations in Area 5 during AprilNovember 2019
- Velocity transect data at several locations in Area 5 over different flow regimes during April-November 2019 Without such calibration and demonstration of model performance, the use of the model for the sediment stability assessment is untested and unreliable.

Commenting Organization: EGLE
General Comment #3: The ASTM and FS should incorporate a dam-out scenario and at a minimum account for potential changes in floodplain boundaries (e.g., previously inundated sediment that will become future floodplain), flooding (e.g., extent of flooding under 2-year and 100-year flows) and associated exposure risks (e.g., residential/recreational use in previously inundated areas).

Commenting Organization: EGLE
General Comment #4: During Phase 2 of the SRI an unknown number of cores were processed in a manner that was inconsistent with standard site protocols. Specifically, cores were opened, split in half and, in some instances, one-half of the core material was homogenized and placed into the sample and the other half was disposed of without being processed. In other cases, staff processed the core halves independently of each other and at different sample intervals. For example, after splitting the core tube the left half was processed in 4" intervals, the right half was processed in 6" intervals, and the two halves were processed separately and not combined. The SRI Report should include a discussion on which cores were impacted by this issue and what, if any, impact the processing issues may have had on total PCB (and other) laboratory results.

Commenting Organization: EGLE
General Comment #5: Prior to conducting the Phase 2 SRI, EGLE communicated concern that there may be a low bias in total PCB concentrations reported by Georgia-Pacific's (GP's) laboratory. EGLE suspected there may be a substantial and systemic low bias in GP's Aroclor results after splits of samples collected by GP and provided to EGLE during the Area 1 Pre-Design Investigation showed a significant low bias when GP's total PCBs via the Aroclor method to EGLE's total PCB via the congener method. More recently, an investigation in Area 4 completed by the EPA and GP definitively concluded that GP's total PCB measurements are biased low and significant adjustments to the analytical methodology is necessary. If total PCB measurements are inaccurate and biased low the nature and extent of contamination and perceived risks in Area 5 may be underrepresented and remedial footprints may be artificially reduced.

EGLE's evaluation of the Respondents data from Area 1 and split samples collected from Area 4 suggests that total TEQ and total PCB exceedances may not be correlated at low detections and in some instances risks associated with total TEQ may drive decision making. Site decision making is predicated on the assumption that addressing risk to total PCBs will adequately address total TEQ risks. This does not appear to always be the case and additional data and more rigorous evaluations are needed to evaluate the degree of correlation between to the two COCs.

The SRI Report should be updated to include a discussion on how the low bias in total PCB concentrations in the Area 5 Phase 1 and Phase 2 SRI data is being accounted for. It is vital that project documents be transparent and complete in conveying site information and discussions. This only further adds to the necessity of the laboratory bias discussion.

SPECIFIC COMMENTS

Commenting Organization: EGLE
Section: 1.4.1.2 **Page #: 1-7** **Lines #: NA**
Specific Comment #1: The text discusses geochronology investigation details for AL-1 and AL-2 but not for AL-3 and AL-4. Expand the discussion of AL-3 and AL-4 geochronology cores based on the information available in the project database.

Commenting Organization: EGLE
Section: 3.6.4.3 **Page #: 3-16** **Lines #: 1-5**
Specific Comment #2: The relative comparison of erodibility index to the critical shear stress for erosion is reasonable – cores with greater critical shear stress for erosion tend to have lower erosion rates (i.e., erodibility index <1). Revise the text to also include a discussion of the results – is there a spatial pattern to the distribution of the less and more erodible cores, does the erodibility correlate qualitatively with any other physical property such as ambient shear stress regime, grain size distribution, etc. Such a comparison will be useful in the eventual use of this data during remedy development.

Commenting Organization: EGLE
Section: 3.8.2 **Page #: 3-18** **Lines #: NA**
Specific Comment #3: Section 3.8.2 acknowledges that mean daily flow at the Kalamazoo River stations has increased over time. Increased daily flows should be accounted for in the remedy for Area 5.

Commenting Organization: EGLE
Section: 3.9 **Page #: 3-21** **Lines #: NA**
Specific Comment #4: The discussion in Section 3.9 proceeds directly from model setup (Section 3.9.1) to model application (Section 3.9.2). For completeness, also include a discussion of model calibration including calibration metrics, calibration periods, and calibration parameters. Discussions of model calibration is standard practice for sediment Superfund documents where modeling is utilized.

Commenting Organization: EGLE
Section: 4.1.2.3 **Page #: 4-2** **Lines #: NA**
Specific Comment #5: Section 4.1.2.3 states that "reoccupied data are from SRI MNR LOE sediment sampling locations that were sampled within about 15 ft of a pre-SRI sampling location." EGLE notes that comparing subaqueous sediment PCB concentrations on a point-bypoint approach to assess the efficacy of MNR is a flawed approach. This site has a demonstrated history of small-scale heterogeneities in PCB concentration, and the ability to directly reoccupy a previous subaqueous sediment core location is near impossible (e.g., boat positioning, GPS accuracy, issues with sampling from the water's surface through the water column, etc.). Any evaluation of temporal trends in total PCB concentrations (utilizing accurate PCB concentration data) should be conducted on an areal basis. This areal extent could be via lake bottom feature, sediment decision management unit (SDU), etc. A point-by-point comparison should not be performed. Furthermore, multiple samples within a single SDU should be used for compositing and to establish that area's "concentration".

Commenting Organization: EGLE
Section: 4.3.5 **Page #: 4-15** **Lines #: NA**
Specific Comment #6: Section 4.3.5. states that the pending avian PRG for Total TEQs is 7,000 ng/kg. EGLE has previously noted concerns regarding the Total TEQ PRG for avian ecological receptors of 7,000 ng/kg, since the avian TRVs (NOAEL=14 ng TEQ/kg/day and LOAEL=140 ng TEQ/kg/day) derived from Nosek et al. (1992) are acute lethality values. Section 5.2.2 of the November 16, 2018 TBERA (Appendix L of the Area 4 SRI) states, "Mortality was observed in birds exposed at a concentration of 140 ng/kg/day, with 57 percent of the birds in this group dying between weeks 15 and 24…Greater than 98 percent embryo mortality was observed in eggs laid by hens exposed at a concentration of 140 ng/kg/day. Based on the observed mortality, reduced egg production, and lower embryo survival at an exposure dose of 140 ng/kg/day, a LOAEL TRV of 140 ng/kg/day and a NOAEL of 14 ng/kg/day were identified from this study." Consequently, a cleanup based on the LOAEL value will potentially result in mortality of half of the resident invertivorous birds, and nearly complete mortality of their eggs. Substituting NOAELs for LOAELs in EPA's method, EGLE estimates the protective avian PRG in this scenario to be 375 ng/kg Total TEQ. Note, avian Total TEQs in the surface soil range from 6.7 to 764 ng/kg and from ND to 2,646 ng/kg in Interval 2 soil, exceeding EGLE's estimated avian PRG. EGLE strongly encourages EPA to reassess the pending avian PRG for Total TEQ.

Commenting Organization: EGLE
Section: 4.4.1 **Page #: 4-17** **Lines #: 31-35**
Specific Comment #7: Revise the text to indicate if the flow used in the regression analyses is the measured flow at Comstock or an estimated flow at the location where the PCB data were collected, and potential artifacts in case the measured flow at Comstock was used. Also comment on the

negative correlation between flow rate and PCB concentrations. As flow rate decreases, travel time increases and consequently, dissolved-phase flux of PCBs from sediment to water column may transfer greater PCB mass to the water column under low flow conditions than under high flow conditions. This is an equally plausible physical explanation of PCB fate and transport in Area 5 and should be acknowledged.

Commenting Organization: EGLE
Section: 4.4.1 **Page #: 4-18** **Lines #: 19-21**
Specific Comment #8: Just as Julian day and temperature are correlated, so are flow rate and temperature due to seasonality in river flow. Revise the text to comment on the potential for multicollinearity and confounded interpretation of the multivariate regression results because of the relationship between river flow rate and temperature. Discussions of the potential for multicollinearity and confounded interpretation of the multivariate regression results is standard practice for sediment Superfund documents where modeling is utilized.

Commenting Organization: EGLE
Section: 4.4.1 **Page #: 4-18** **Lines #: 32-35**
Specific Comment #9: Although PCB concentrations at both locations show similar trends with the various independent variables, there is an apparent increase in PCB concentrations from Trowbridge to Lake Allegan Inlet. Although not over same spatial extent as the LTM data, mean and median values measured during the HyST/OPTICS program in 2019 (values in Table 4-14) also show a similar trend - increasing PCB concentrations from Station 1 to Station 2. Revise the text to mention this spatial trend and potential insights into fate and transport processes from this trend.

Commenting Organization: EGLE
Section: 4.4.2 **Page #: 4-20** **Lines #: 22**
Specific Comment #10: It is not clear why a linear trend should be expected between total suspended solids (TSS) and Julian Day; revise the text to clarify. The apparent trend of higher concentrations towards the middle of the year may correlate with seasonality in primary production – standard analytical methods for TSS also capture algal dry matter. Therefore, the presence of algal dry matter may be a plausible explanation for the apparent seasonality (higher values mid-year) in TSS.

Commenting Organization: EGLE
Section: 4.4.5 **Page #: 4-21 and 4-22** **Lines #: NA**
Specific Comment #11: The findings from the HyST/OPTICS program described in the last two paragraphs of this section will benefit from a presentation of the data/analyses. Revise the report as appropriate.

Commenting Organization: EGLE
Section: 5.3 **Page #: 5-3** **Lines #: 7**
Specific Comment #12: Revise/clarify use of the self-contradictory term "fine sediment bedform"; bedforms are associated with sand transport rather than the transport of fine sediment which is a term used to refer to silts and clays.

Commenting Organization: EGLE
Section: 6.1 **Page #: 6-1** **Lines #:NA**
Specific Comment #13: The first paragraph states, "As specified in an agreement between USEPA

and Georgia-Pacific, the BHHRA for Area 5 has focused on the primary exposure pathway of concern, consumption of fish by sport anglers and subsistence anglers (ARCADIS 2012)." The citation provided is for the Area 1 SRI Report. EGLE would appreciate GP providing additional information that supports the statement in the text.

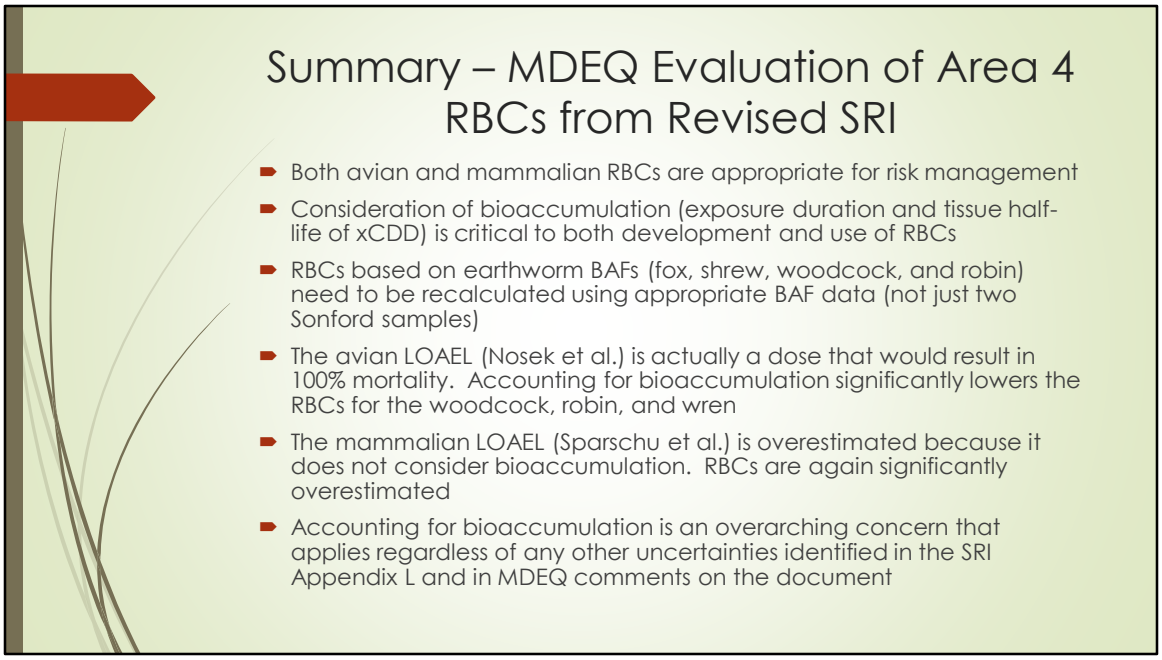
Commenting Organization: EGLE
Section: 6.1 **Page #: 6-1** **Lines #:**
Specific Comment #14: The first paragraph states that risk calculations for anglers are based on just two Aquatic Biota Sampling Areas (ABSAs), ABSA-09AC.1 (flowing RM 43.6 to 42.6) and ABSA-09AC.2 (lake RM 36.9 to 35.9), and that the data from both ABSAs were combined. The data from the two ABSAs should be analyzed both separately and combined. The purpose of collecting fish tissue in the flowing section and the impounded section should be to identify potential differences in uptake from the scoured bottom and the depositional area. The Baseline Human Health Risk Assessment (BHHRA) should be revised to show risks from both areas.

Commenting Organization: EGLE
Section: 6.1 **Page #: 6-1** **Lines #:**
Specific Comment #15: Tables indicate that fish consumption cancer risk for both subsistence and sport fisher appear significantly lower than was reported in the 2003 BHHRA (still greater than EGLE acceptable, but lower than 2003). Have the fish tissue concentrations dropped significantly? Section 7 lists some statements about tissue concentration differences over the years, but it adds no support for those statements.

Commenting Organization: EGLE
Section: 6.2 **Page #: 6-15** **Lines #: 7-15**
Specific Comment #16: The first full paragraph states that Site-wide PRGs for Area 5 were based on the Area 4 TBERA (11 mg/kg TPCBs; 1,000 ng/kg mammalian TEQ; 7,000 ng/kg avian TEQ), and, "Therefore, a formal TBERA quantitatively assessing risk is not warranted for Area 5." The paragraph goes on to state that this was discussed in a 4/23/20 Work Group meeting with EPA, EGLE, GP, and consultants. EGLE has significant concerns with the Area 4 TBERA, that have been laid out in great detail to EPA, GP, and Wood in writing, calls, and meetings. EGLE's technical concerns with the Area 4 TBERA show that the PRGs selected for PCBs and dioxins were not scientifically defensible and will not be protective. All those comments are now applied to the Area 5 TBERA. Additional information previously provided by EGLE on the Area 4 TBERA are included as Attachment 1.

Area 4 – TRV/RBC Comments

Supporting Information



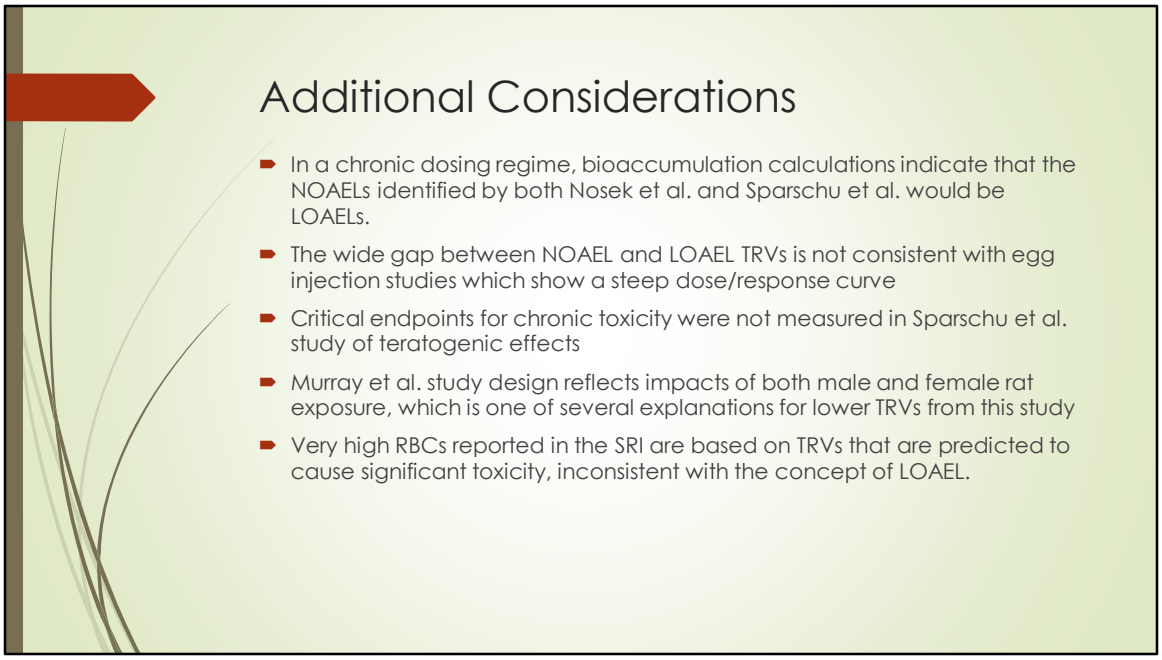
1. Wood/GP have stated that the avian RBCs were not appropriate because of uncertainty in the TEFs. However, the avian TEFs were selected from appropriate studies that were evaluated by a World Health Organization panel of international experts and found to be suitable for use as avian TEFs. The derivation of avian RBCs is equally as valid as the derivation of mammalian RBCs.

2. Wood/GP used short-term studies to derive TRVs. When assessing bioaccumulative contaminants, it is critical to utilize studies that include steady-state tissue concentrations. A dose that may not impact a mammal after a 10-day exposure may kill that same animal after 90-days.

3. Earthworm BAFs are both the foundation of, and the risk drivers for, the derivation of RBCs. The earthworm BAFs used by Wood/GP are orders of magnitude too low because they were derived through a very complex set of mathematical manipulations performed on only two soil samples from the Sonford, MS site (Sonford data was put through normalization/denormalization/renormalization for soil TOC and tissue lipids, along with weighting/deweighting/reweighting TEFs based on the mixtures of D/Fs). The current RBCs (and the potential remediation) are wholly based on two

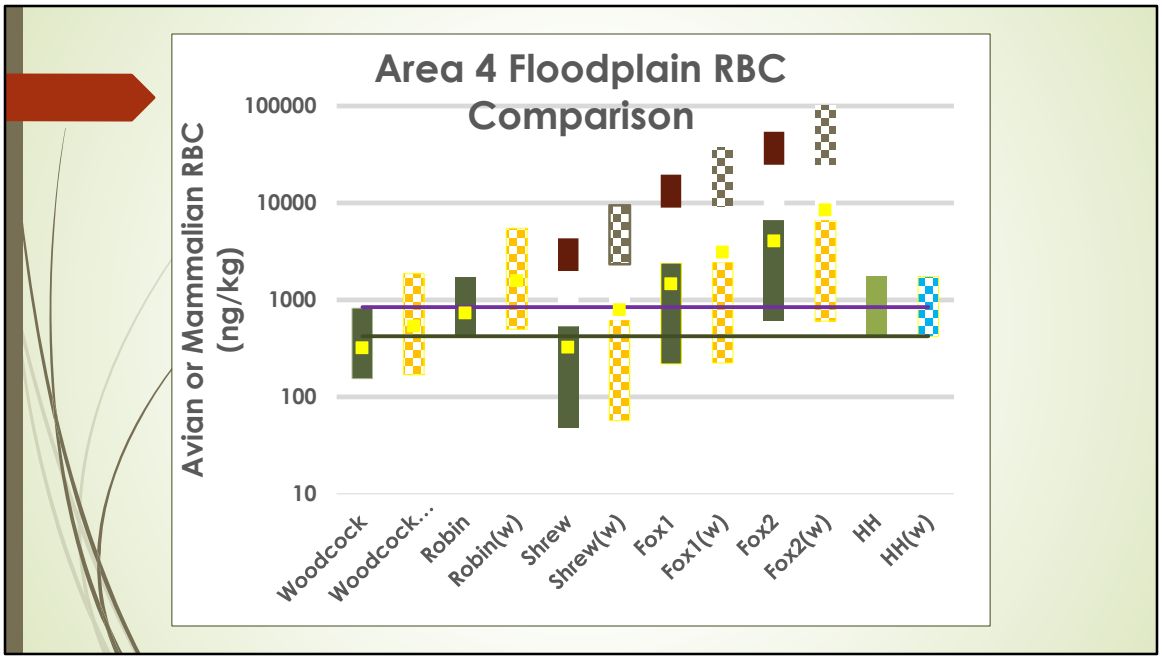
soil samples from a site in another state. This approach is unacceptable.

4. MDEQ has evaluated Wood/GP's bases for TRVs for both avian and mammalian receptors and has determined that RBCs derived from these TRVs are not protective. The following slides summarize this evaluation, and slide notes also cross reference Excel spreadsheets that provide details of the approaches and input parameters for all calculations. The Excel spreadsheets are active to provide transparency.



1. "LOAELs" from Nosek et al. (14 ng/kg-d) and Sparschu et al. (30 ng/kg-d) are in an exposure range where adverse effects are anticipated. However, Wood/GP used the Nosek et al. value as a NOAEL in their derivation of RBCs. The Sparschu et al. value is an exposure concentration that would result in significant adverse effects after a chronic exposure. Since significant toxicity was observed at the higher short-term exposuress, these LOAELs will significantly overestimate and yield RBCs that are not protective.

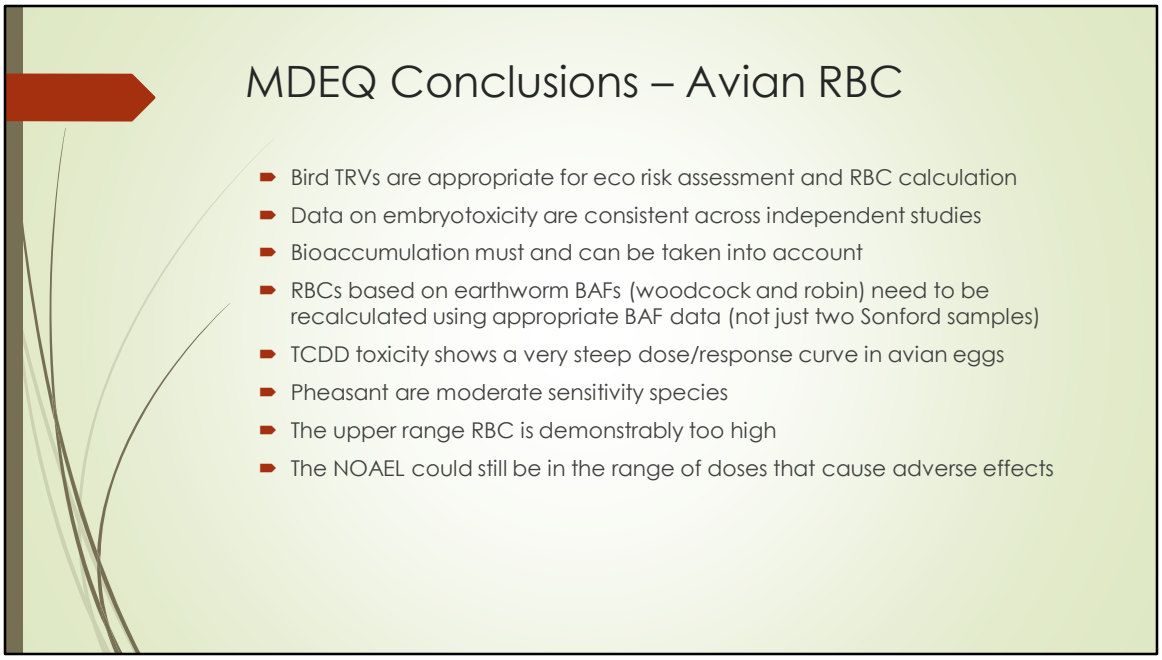
2. MDEQ stresses the importance of using the Murray et al. TRV values because the three-generation study with continuous feeding exposure of both male and female rats clearly shows that longer-term exposure (as will happen in the Kalamazoo floodplain) shows that accumulation of these bioaccumulative compounds yields toxic impacts at concentrations orders of magnitude lower than the values derived from the Sparschu et al. 10-day, short-term exposure of already-pregnant rats. These facts indicate that the NOAELs used by Wood/GP are likely to still produce adverse impacts.



1. This chart is an overall summary of the analysis that compares RBCs calculated by Wood/GP without consideration of bioaccumulation (checkered bars) to revised RBCs calculated by CDMS/MDEQ taking into account impacts of bioaccumulation on TRV estimates (solid bars). The data and calculations are provided in the accompanying Excel file titled: "Revised_Area4_Floodplain_RBC_Summary_060418".
2. The yellow squares are the geometric means across the RBC estimates (NOAEL and LOAEL based (ecological risk). Geometric means were not calculated for the HH RBCs.
3. The (w) following receptors on the x-axis indicate that values in the chart are from Wood/GP.
4. Each bar for ecological receptors represents NOAEL and LOAEL estimates from a single TRV source. For example, the bottom of the solid **ocher bar** for the woodcock is the NOAEL and the upper end is the LOAEL derived from TRVs from Nosek et al. as developed by CDMS/MDEQ using bioaccumulation. The checkered **ocher bar** for woodcock(w) is similar, but is developed from Nosek et al. by Wood/GP without consideration of bioaccumulation.
5. For mammals (shrew and fox) the **ocher bars** represent TRVs from Murray et al., and the **dark blue** bars represent TRVs from Sparschu et al. For the fox, the

dietary assumptions of both soil to bird (fox1) and insect to bird (fox2) are presented. Again, solid bars represent TRVs adjusted for bioaccumulation.

6. The solid horizontal lines represent 420 ppt, the RBC estimate based on a cancer risk for recreational visitors of 1 in 100,000, and 840 ppt, a midpoint of values based on cancer and non-cancer endpoints. Calculations of RBC used spreadsheets provided by Wood/GP with the only modification being revised TRVs (see following slides).

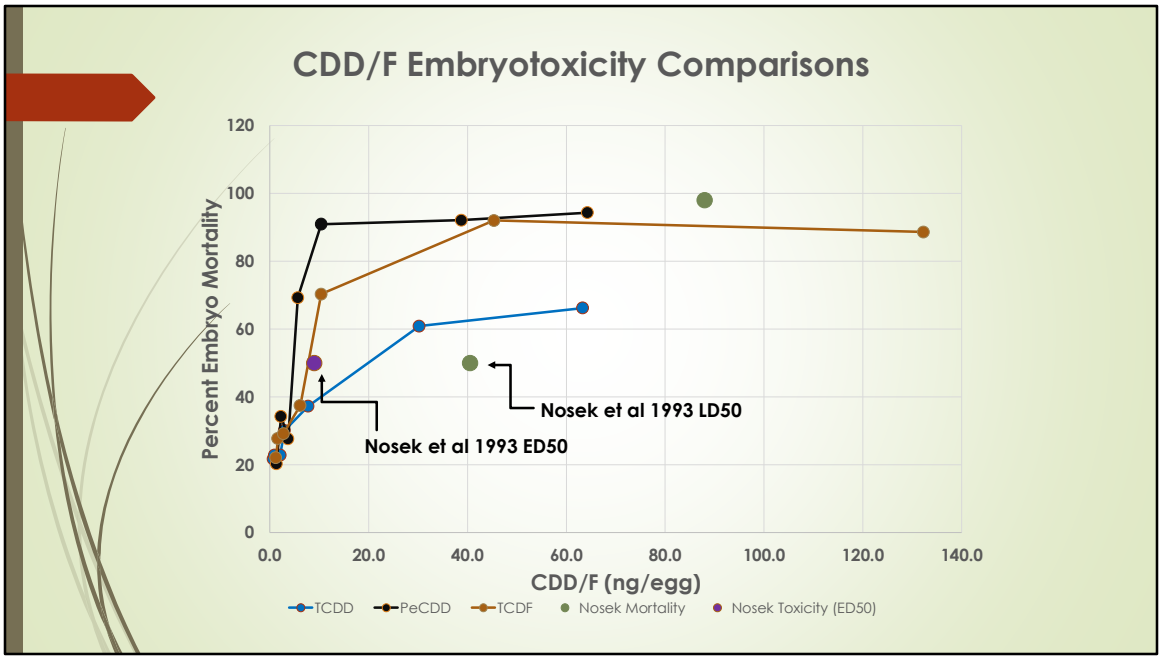


1. Details of the analysis of avian TRV are provided in the following slides.

2. Data and calculations for all of the analysis are provided in the accompanying Excel file titled: “Embryotoxicity_Cohen-Barnhouse_053118”.

3. Note that BAFs were not altered in the calculations of RBCs, and, as already shown, the earthworm BAFs are not appropriate.

4. Additional discussion will be needed to determine appropriate BAFs for uptake of xCDD/F into earthworms.

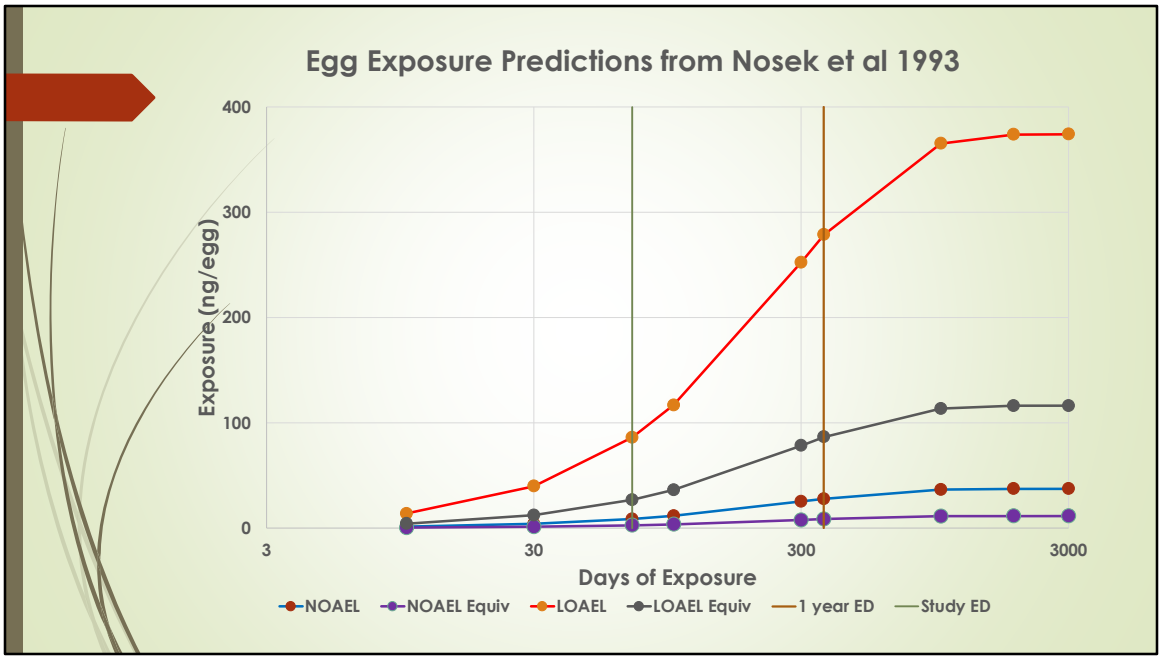


1. This figure uses literature data to demonstrate the steep dose response curve for egg injection studies. The data and calculations are provided in the accompanying Excel file titled: "Embryotoxicity_Cohen-Barnhouse_060418".

2. For PeCDD, control to 100% mortality occurs over a range of 0 to 10 ng/egg.

3. An LD_{20} (a non-conservative endpoint to use to quantify a lethality LOAEL) would be in the range of 2 ng/egg (control mortality was about 20 percent so that an increase of 20% would occur at about 3 ng/egg).

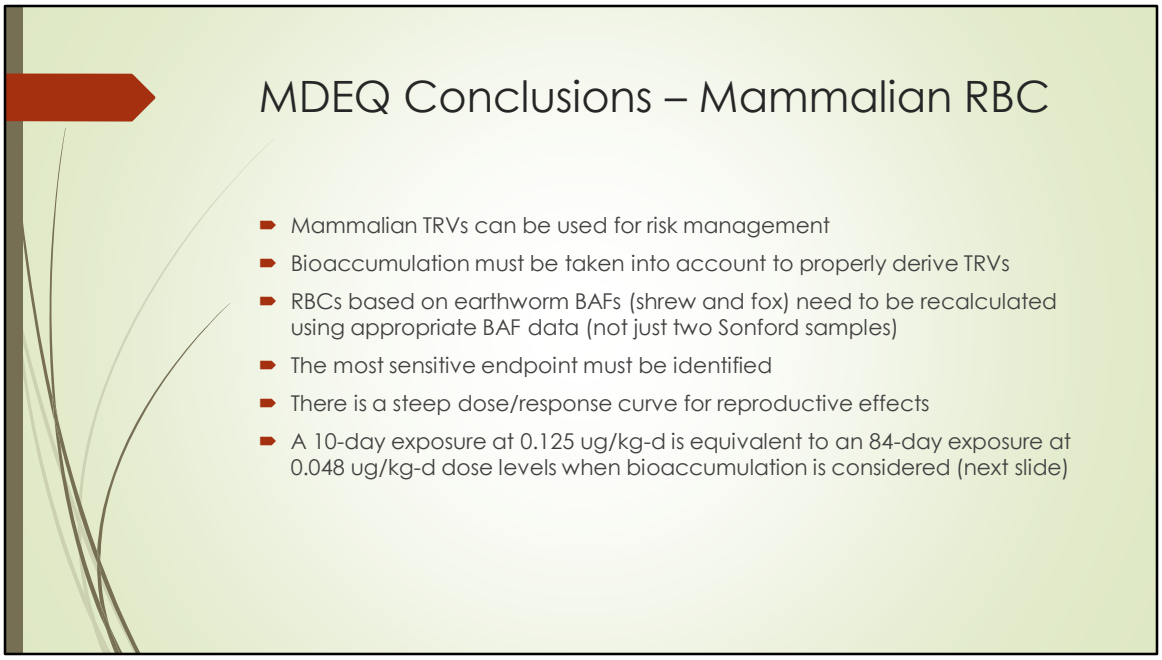
4. The egg injection study results compare well with results of hen dosing reported by Nosek et al. The ED_{50} for hen toxicity occurs at a slightly higher dose than does embryo mortality. Further, any LD_{50} for embryo mortality is consistent with almost complete mortality in egg injection studies. Exposure rate for hens that result in a dose to eggs in the range of a few ng/egg are likely to result in significant impacts.



1. This chart plots predicted body burdens for hens at exposure rates used in the Nosek et al. study. Data and calculations are provided in the accompanying Excel file titled: "Embryotoxicity_Cohen-Barnhouse_060418".
2. Body burden is used as a surrogate for plasma concentrations since the volume of distribution of xCDD in pheasants is not known. Nosek et al. reported impacts to embryos in terms of percent body burden transferred to egg yolk. At a rate of 140 ng/kg-d for 70 days, body burden calculations suggest a dose of nearly 100 ng/egg.
3. For the same exposure duration, a dose rate of 14 ng/kg-d is predicted to be within the lower range of doses that may cause adverse effects.
4. The Study ED line shows the point in time where investigators ceased dosing.
5. Predicted body burden is much higher if exposure (140 ng/kg-d) is assumed to continue to for a year (one year is used because pheasants are not expected to lay until the next year's breeding season). Doses of close to 300 ng/egg are anticipated under this scenario.
6. The study NOAEL dose rate (14 ng/kg-d) suggests impacts in the range of 20 ng/egg. To recalculate a RBC based on body burden, an exposure rate that results in a similar estimate of ng/egg after 365 days of exposure (as was reported by Nosek et al. after 70 days of exposure) was estimated. This dose rate (43 ng/kg-d)

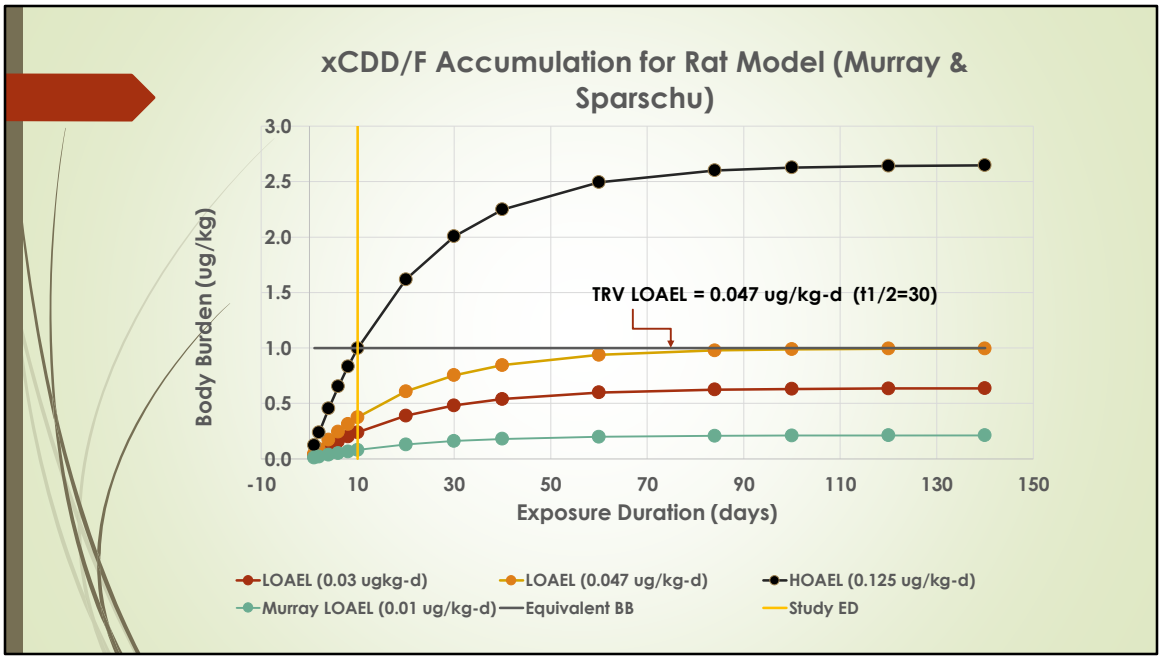
is recommended as a upper range estimate of LOAEL (i.e., a dose rate that is likely to result in significant toxicity).

7. A dose rate for a one-year exposure duration that predicts the same body burden as estimated for a 70 day exposure is 4.3 ng/kg-d, which is only 31 percent of the NOAEL generated by the Nosek et al. study. This 4.3 ng/kg-d dose rate is recommended as a NOAEL for chronic exposure.
8. Note that estimates for ng/egg for both NOAEL and LOAEL may fall above the range of doses that cause toxicity in injection studies.



1. Details of the analysis of mammalian TRV are provided in the next slides. Data and calculations for all of the analysis are provided in the accompanying Excel file titled: "xCDD_Accumulation_Rat_Predictions_060418".

2. Note that the BAFs were not altered in the calculations of RBCs, and, as already shown, the earthworm BAFs are not appropriate. Additional discussion will be needed to determine appropriate BAF for uptake of xCDD/F into earthworms.



1. This chart plots predicted body burdens for rats at exposure rates used in the Murray et al. and Sparschu et al. studies. Data and calculations for all of the analysis are provided in the accompanying Excel file titled: "xCDD_Accumulation_Rat_Predictions_060418".
2. Body burden is used as a surrogate for plasma concentrations since volume of distribution of xCDD in rats is not known.
3. Calculations assume a half-life for xCDD of 30 days. This assumption is reasonable for lower chlorinated congeners, but likely underestimates half-life for congeners with higher levels of chlorination.
4. Sparschu et al. reported impacts after 10 days of exposure of embryos at a dose rates of 0.125 ug/kg-d and higher. Toxicity was not observed at a dose rate of 0.03 ug/kg-d over the same time period. The short exposure duration does not allow for bioaccumulation and significantly underestimates body burden after longer exposure periods.
5. The Study ED line shows point in time where investigators ceased dosing.
6. Predicted body burden is much higher if exposure is assumed to continue for several half-lives. To recalculate a RBC based on body burden, an exposure rate was estimated that results in a body burden after 100 days of exposure that is similar to the body burden predicted at 10 days. This dose rate (0.047 ng/kg-d) is

recommended as a upper range estimate of LOAEL (i.e., a dose rate that is likely to result in significant toxicity).

7. Similarly, a dose rate of 0.011ug/kg-d for a 100 day exposure duration predicts the same body burden as estimated for a 10 day exposure, which is essentially the same as the LOAEL estimated in the Murray et al. study.
8. Recommendations for mammalian TRVs are therefore: NOAEL = 0.001 ug/kg-d (Murray et al.); LOAEL = 0.01 ug/kg-d (Murray et al. and Sparschu et al.); LOAEL (upper range estimate) = 0.047 ug/kg-d (Sparschu et al.).

Summary

Preliminary Revised TBERA RBCs using results of bioaccumulation calculations

(subject to change with revised earthworm BAF)

	Woodcock	Robin	Shrew	Fox1	Fox2	HH
NOAEL	154	416	48	218	605	
LOAEL	665	1286	483	2177	6050	
LOAEL (upper)			1449	6531	18149	
Rec HH CSF						420
Rec HH Rfd						1320
Geomean	320	731	323	1457	4050	NA

All units in ng/kg TCDD equivalents in soil

1. Revised RBCs are designated “preliminary”, because revisions to the earthworm BAFs are required before any avian or mammalian RBC can be calculated.
2. The corrected earthworm BAF will significantly affect the RBCs for woodcock, robin, shrew, and fox, the species most at risk for adverse effects of TCDD equivalents in soil.

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				The RBCs for Kalamazoo were derived using site-specific data and inputs. However, the RBCs were based on TRVs that were not appropriate. The RBCs derived for the Tittabawassee River were also derived using site-specific data and inputs, but they are in line with estimates from the scientific literature. The EPA established risk management principles to make scientifically sound and nationally consistent risk management decisions at Superfund sediment sites. The RBCs for the Kalamazoo River floodplain are not expected to be identical to those from the Tittabawassee River floodplain, but they are expected to be consistent and in the same approximate range.
69.	L4-2	Appendix L, Section 4.2	Depth intervals	The inconsistency between depth intervals for tPCB and the smaller data set for tPCB, DLC TEQ, and D/F TEQ is not supported. Applying surface (0 to 12") results to estimate DLC and D/F TEQ to the deeper interval (12" to 24") may not be appropriate since timeframes for deposition in former impoundment sediments presumably vary with depth, and for D/F, no data are available for this interval. The solution proposed in the TBERA is to examine tPCB and DLC TEQ over a 0 to 24-inch interval and D/F TEQ over a 0 to 12 inch interval. Since, as stated in the text, tPCB concentrations decrease with depth, this approach may underestimate exposure to receptors, particularly for birds for which DLC are particularly important and will also decrease in concentration with depth. A parallel set of calculations using a 0 to 12 inch interval should be included to demonstrate the impact of the approach using disparate depth intervals for PCB/DLC and for D/F TEQ. Include the calculations and revise the text, tables, and figures accordingly.
70.	L4-7 and L4-11	Appendix L, Sections 4.4.2 and 4.5.3	For the PCB (PCB and DLC TEQ) evaluation, the available house-wren egg PCB data collected by MSU and floodplain soil PCB data collected by BBL in the former Trowbridge Impoundment were considered in developing the BAF for estimating egg tissue concentrations.	House wren diet composition indicates that they are the least susceptible to exposure to tTEQ in soil. As insectivores, their exposure is largely or wholly absent of soil and earthworm intake, which are primary sources of exposure to other avian receptors. The TBERA must indicate that risks and RBCs for this species, and others in the same guild, cannot be weighted equally with risks and RBCs derived for vermivorous species.
71.	L5.2 and L5.2.2	L5-2 and L5.4	"PCB 105 and 118, two of the dioxin-like PCB congeners studied, induced AHR-mediated effects in ringnecked pheasant (Phasianus colchicus) (a moderate sensitivity species (emphasis added)) and	These conflicting statements must be reconciled. In general, available evidence does not suggest any ability to determine sensitivity based on systematic relationships. Cite evidence that pheasant is a moderately sensitive species (e.g. Nosek et al. 1993, "We conclude that embryo mortality is the most sensitive sign of TCDD toxicity in the ring-necked pheasant following in ovo exposure. The ring-necked pheasant embryo is less sensitive than the chicken (*Gallus domesticus*) embryo and more sensitive than the eastern bluebird (*Sialia sialis*) embryo to TCDD toxicity. Farmahin et al. 2013, Ile324_Ala380 and Val324_Ser380 genotypes confer intermediate sensitivity to DLCs in birds. We compared ligand-induced transactivation

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			Japanese quail (Coturnix japonica) (a low sensitivity species) at levels equivalent to or greater than chickens (a highly sensitive species)." and "In addition, the ring-necked pheasant is a gallinaceous bird, which is generally considered to have greater sensitivity to DLC exposures than other avian species based on molecular characteristics of the ligand binding domain (Powell et al. 1996a and 1997; Brunström and Reutergardh, 1986; Brunström 1988; Seston 2009)."	function of full-length AHR1s from chicken, common tern, ring-necked pheasant (*Phasianus colchicus*; Ile324_Ala380) and Japanese quail (*Coturnix japonica*; Val324_Ala380); Head and Kennedy 2009, chicken and pheasant EC50 and LD50 differ by an order of magnitude with chicken being the more sensitive species. Turkey and quail are also gallinaceous species and are two orders of magnitude less sensitive than chicken). Remove unjustified/unsupported speculation in Section 5.2.2.
72.	L5-5 and L5-9, etc.	Appendix L, Sections 5.2.2, 5.3.2, 5.3.3, 6.1, 6.3.1, 6.4.4, 6.4.5, 6.5.1, 6.5.2, 7 Table 5-2	Page L5-5: "As mortality is the most sensitive response to D/F by pheasants (Elliot et al., 1996), it is likely to provide conservative results for assessing risk to other avian species." Page L5-9: "Because the Murray et al. (1979) reproductive endpoints are over an order of magnitude lower than reproductive effect levels observed in all the other studies reviewed, use of this NOAEL TRV selected for mammals may overstate toxicity because it is not bounded by other studies and is an artifact of the doses selected for testing (i.e., 1 and 10 ng/kg BW/day)."	The quoted statement regarding Elliot et al. 1996 is difficult to reconcile with a LOAEL that is greater than the LD_{50}. Over half of the birds in the studies died after dosing. This statement is also inconsistent with the complaint later in the report that implies that the order of magnitude dose range in the Murray et al. study creates an "artifact" in TRVs. The "LOAEL" derived from the Nosek et al. study is based on an extreme dose that is highly likely to mask less dramatic, but still quite adverse effects that would occur at lower levels of exposure. The suggestion that because the endpoint of the study is mortality, the "LOAEL" will be protective is entirely incorrect. Sub-lethal adverse effects will occur at lower levels of exposure and the Nosek study does not derive a LOAEL that is useful in determining a protective RBC. That is, with soil concentrations at the LOAEL, both high and mid-sensitivity avian receptors would be eliminated (killed); information in the study is insufficient to determine where, in the interval between the NOAEL and the extreme LOAEL, an appropriate LOAEL might fall. An appropriate toxicological assessment of LOAEL-based RBCs must be included to acknowledge the substantial uncertainty in them as "protective" and "conservative" levels. The Nosek study is not appropriate for establishing protective soil concentrations, and LOAEL-based RBC must be considered non-protective for chronic reproductive and developmental impacts. Additionally, during the 5/8/18 in-person meeting between EPA, AMEC/GP, and MDEQ in Kalamazoo, MDEQ detailed the necessity for including bioaccumulation and depuration half-life in the selection of TRVs for bioaccumulative compounds such as D/F and PCBs. MDEQ's 6/11/18 email to AMEC/GP and EPA (Peabody to Draper, Fogell, and Dillon, subject: Area 4 WG Meeting Presentation) included the PowerPoint presentation (along with complete notes for each presentation slide) and three Excel spreadsheets with all step-by-step calculations to demonstrate that using short-term studies such as the Nosek study will yield RBCs that are not protective.
73.	L5-10, etc.	Appendix L, Sections 5.2.2, 5.3.2, 5.3.3, 6.1, 6.3.1, 6.4.4, 6.4.5, 6.5.1, 6.5.2, 7 Table 5-2	First full paragraph	The document contains erroneous, scientifically unsupported statements in Appendix L concerning toxicological studies (e.g, Murray) that need to be removed from the document and replaced as specified in below and in subsequent comments. The citation (Sparschu et al. 1971) used for derivation of one set of mammalian TRVs is only a 10-day acute study. EPA guidance indicates that chronic studies should be used when available as a basis for evaluation of remedial alternatives. RBCs calculated based on TRVs from this study are, predictably, orders of magnitude higher that RBCs for any other receptor and will not be protective for avian or small mammalian receptors. Appropriate caveats concerning this study, along with an unbiased acknowledgement of multiple studies in the literature that show TRVs well below (e.g. more than an order of magnitude lower) than TRVs derived from Sparschu et al. and that fall in and below the range of TRVs derived from the study by Murray et al that continues to form the basis for EPA evaluation of ecological risks for mammalian receptors. The Murray et al. study was used as the source of TRVs for the Tittabawassee River ecological work. Such discussion must be included everywhere in the TBERA where used as the source of TRVs for the Tittabawassee River ecological work. Such discussion must be included everywhere in the TBERA where TRVs are discussed. Section identified for revision are included in column 3. See also additional specific comments on Appendix L below

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				The TBERA states that the TRVs developed using Murray et al. (1979) yielded endpoints ten times lower than other studies, and that it may overstate toxicity. However, the TBERA does not account for the fact that the Murray study was a long-term multigeneration study and was therefore significantly more sensitive and representative than the other shorter studies reviewed. Additionally, as demonstrated during the 5/8/18 in-person meeting between EPA, AMEC/GP, and MDEQ in Kalamazoo, MDEQ detailed the necessity for including bioaccumulation and depuration half-life in the selection of TRVs for bioaccumulative compounds such as D/F and PCBs. MDEQ's 6/11/18 email to AMEC/GP and EPA (Peabody to Draper, Fogell, and Dillon, subject: Area 4 WG Meeting Presentation) included the PowerPoint presentation (along with complete notes for each presentation slide) and three Excel spreadsheets with all step-by-step calculations to demonstrate that using long-term studies such as the Murray study will yield RBCs that include the effects of bioaccumulation and are protective. Moreover, as discussed below, several chronic exposure studies did, in fact, indicate TRVs at and even below the TRVs developed from the Murray et al. study. A 10-day study, by Sparschu et al. (1971) assessing teratogenic effects in partial-term fetuses cannot be used assess to the sustainability of small mammal populations, nor can it be used to assess the impacts of bioaccumulation. The focus on teratogenicity resulted in a short gavage exposure of adult (136 days old) pregnant rats for only 10 days (from days 6 to 15 of gestation), and limited outcomes were used to assess toxicity. No males were exposed to 2,3,7,8-TCDD, so there is no inclusion of impacts to sperm which have been demonstrated at the concentrations tested in the Murray study (Latchoumycandane and Mathur 2002). The mothers were decapitated at gestation Day 20 to assess the fetuses. While the study was an assessment of sub-lethal effects, it was not a chronic study, it did not include male exposure, and it did not include gestation to full-term. Clearly, the Sparschu study does not support RBC that are protective for any receptor addressed in the TBERA and, thus, for any additional species represented by these receptors. Sparschu did report significant toxicity (e.g., fetal resorptions) starting at a dose (0.125 ug/kg-d) similar to the dose reported by Murray (0.1ug/kg-d). Sparschu did not, however, examine other endpoints, such as fertility, litter size, gestational survival, post-natal survival, post-natal body weight, all of which were reported by Murray at lower doses in the second and third generations. Those long-term effects resulted from bioaccumulation of 2,3,7,8-TCDD. The Sparschu study was by design, incapable of observing chronic toxicity that occurs at the lowest effective doses. Finally, the dosing regimens for the Sparschu and Murray studies were quite different – once daily doses administered via gavage during the middle 10 days of the normally 22-day gestation period versus continuous daily doses in food starting 90-days prior to pregnancy and continuing for three generations. Cumulative impacts of continuous exposure to TCDD could only be observed the Murray study. Additionally, the Murray study notes that pharmacokinetic studies have indicated that 2,3,7,8-TCDD approaches steady-concentrations in the body in 90 days (Murray cites Rose et al. 1976). The Murray study exposed both male and female rats from 7 weeks old (approximately 49 days) for 90 days prior to mating and continued to feed TCDD-dosed food to the mothers and offspring for the duration of the three-generation study. The TCDD body burden had likely reached steady-state before the rats were impregnated. The results of the Murray paper are representative of long-term exposure of mammals to 2,3,7,8-TCDD. Endpoints assessed by Sparschu are important for describing some aspects of short-term TCDD toxicity, but they are not endpoints that delimit LOAELs or NOAELs. The three generation, reproductive animal study of Murray is notably more powerful. Following EPA's 1997 ERAGS (EPA 540-R-97-006), the Sparschu study must not be given much if any weight in selecting RBCs for tTEQ for use in alternatives analysis. This ERA guidance states that that reproduction, growth, and survival are the key endpoints for consideration (Section 2.5 Assessment & Measurement Endpoints), and while teratogenicity is a viable endpoint, it accounts for only a fraction of possible effects on successful reproduction. Finally, hierarchy of preference is given for chronic effects (e.g., lifetime, multigenerational) over sub-chronic (less than lifetime) effects, over acute, short-term effects (Exposure Duration, Section 1.3.1 Preferred Toxicity Data). Sparschu falls into the realm of short-term and would typically not be used for setting chronic TRVs. With all its deficits for developing appropriate TRVs for TCDD, the Sparschu study does not meet criteria for establishing either chronic LOAELs or NOAELs for TCDD. In other comments, MDEQ indicates that this EPA document is labeled "do not cite or quote" and should be

removed. The table below is included simply to show that evidence was available from multiple studies to inform the TBERA on the range of NOAEL/LOAEL values in the literature. The EPA report in question should be removed from TBERA along with any quotation(s).

Latchoumycandane, C. and Mathur, P. Effects of vitamin E on reactive oxygen species-mediated 2,3,7,8-tetrachlorodibenzo-p-dioxin toxicity in rat testis, *Journal of Applied Toxicology*, 22, pg. 345-351, 2002.

Murray, et al., Three generation reproduction study off rats given 2,3,7,8- Tetrachlorodibenzo-p-dioxin (TCDD) in the diet, *Toxicology and Applied Pharmacology*, Vol. 50 (2), pgs. 241-252, 1979.

Rose, J.Q., J.C. Ramsey, T.H. Wentzler, R.A. Hummel, and P.J. Gehring. 1976. The fate of 2,3,7,8-tetrachlorodibenzo-p-dioxin following single and repeated oral doses to the rat. *Toxicol. Appl. Pharmacol.* 36, 209-226.

Sparschu, et al., Study of the teratogenicity of 2,3,7,8-Tetrachlorodibenzo-p-dioxin in the rat, *Food and Cosmetic Tox.* 9(3), pg., 405-412, 1971.

EPA. 1997. Ecological Risk Assessment Guidance for Superfund: Process for Designing and Conducting Ecological Risk Assessments, Interim Final, EPA 540-R-97-006, 1997.

For reference, all of the following LOAEL/LOEL values were taken from an EPA report ***referenced in the TBERA*** (EPA. 2010. *EPA's Reanalysis of Key Issues Related to Dioxin Toxicity and Response to NAS Comments* EPA/600/R-10/038A). Clearly, LOAELs (and NOAELs found in the same report) are consistent with Murray et al., particularly for chronic studies for reproductive endpoints. In other comments, MDEQ indicates that this EPA document is labeled "do not cite or quote" and should be removed. The table below is included simply to show that evidence was available from multiple studies to inform the TBERA on the range of NOAEL/LOAEL values in the literature. The EPA report in question should be removed from TBERA along with any quotation(s).

Summary of Available Studies for Mammalian TRVs

LOAELs less than those developed using Sparschu et al. and in the range of those developed using Murray et al.

Reproductive Endpoints

Study	Year	Species	TRV	Type	Comment
Franc et al.	2000	Rat	30	LOAEL	Increased liver weight, decreased thymus weight
Hochstein et al.	2001	Mink	2.65	LOAEL	Reduced kit survival. Mink and Shrew in Same Order in Class Mammalia
Hutt et al.	2008	Rat	50	LOAEL	Only one dose used in study. Fewer normal pre-implantation embryos
Ikeda et al.	2005	Rat	16.5	LOAEL	Decreased ventral prostate development, altered sex ratio (fewer males)
Latchoumycandane and Mathur	2002	Rat	1	LOAEL	Reduced sperm production, decreased reproductive organ weights
Murray et al.	1979	Rat	10	LOAEL	Decreases in fertility, number of live pups, gestational survival,

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					postnatal survival and postnatal body weight
Shi et al.	2007	Rat	0.71	LOAEL	Decreased estradiol levels
Yang et al.	2000	Rhesus Monkey	17.86	LOAEL	Increases in endometriosis and implant diameters, and cytokine dysregulation
Developmental Endpoints					
Bell et al.	2007	Rat	2.4	LOAEL	Delayed BPS
Franczak et al.	2006	Rat	7.14	LOAEL	Decreased serum estradiol
Hojo et al.	2002	Rat	20	LOAEL	Abrogation of sexually dimorphic neurobehavioral responses
Kattainen et al.	2001	Rat	30	LOAEL	Impaired tooth development
Keller et al.	2007	Mouse	10	LOAEL	Studies conducted with three strains of mice
		Mouse	10	LOAEL	Studies conducted with three strains of mice
		Mouse	10	LOAEL	Reduced number of serotonin-immune reactive neurons
Kuchiiwa et al.	2002	Mouse	0.7	LOEL	
Li et al.	2006	Mouse	2	LOAEL	
Markowski et al.	2001	Rat	20	LOAEL	Lowest dose administered, single acute
Miettinen et al.	2006	Rat	30	LOAEL	Lowest dose administered, dental caries
Ohsako et al.	2001	Rat	50	LOAEL	Reduced anogenital distance
Chronic (noncancer)					
Cantoni et al.	1986	Rat	1.43	LOAEL	Increased coproporphyrin excretion
Hassoun et al.	2002	Rat	2.14	LOEL	Increase superoxide anion, lipid peroxidation, DNA SSBs in liver/brain
Maronpot et al.	1993	Rat	35.7	LOAEL	Increased liver weight and lesions
NTP	1982	Rat/Mouse	1.4	LOAEL	Liver lesions (mice)
NTP	2006	Rat	2.14	LOAEL	Increased liver weight, hepatocellular hypertrophy, alveolar/bronchiolar epithelial metaplasia
Sewall et al	1993	Rat	3.5	LOEL	Decreased EgFR B_{max} levels
Sewall et al.	1995	Rat	35	LOAEL	Decreased T4
Toth et al.	1979	Mouse	1	LOAEL	Skin lesions, amyloidosis (lethal)
Vanden Heuvel et al.	1994	Rat	1	LOEL	CYP1A1 induction

74.	L5-8 to L5-10, etc.	Appendix L, Sections 5.2.2, 5.3.2, 5.3.3, 6.1, 6.3.1, 6.4.4, 6.4.5, 6.5.1, 6.5.2, 7 Table 5-2	Inaccuracies and citation errors in both sections	The TBERA adds a secondary set of dietary D/F TEQ TRVs, after stating that the Murray et al (1979) TRVs are too low. The Sparschu et al (1971) study is introduced, and the TBERA states that the Sparschu study had a similar ranking score to the Murray study. While the Sparschu study has some value for determining acute exposure risks, it provides no information relevant to developing TRVs based on chronic exposure. In a 2004 ecological risk assessment for the Tittabawassee River floodplain assessing D/F risks, only the Murray study was found appropriate and used to develop TEQ TRV RBCs for the shrew and the red fox (Galbraith Environmental Services LLC, Prepared for MDEQ, 2004) as well as Hazard Indices (HI). Under section, 4.2.2 Insectivorous and Carnivorous Mammals (2004 Assessment) the analysis below is provided.

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				Sample et al. (1996) reviewed the laboratory studies in which mammals were dosed with PCDD/PCDFs. Only one study subjected a mammal (the laboratory rat) to contaminant over an extended period and quantified the effects on reproduction: Murray et al. (1979) subjected three generations of rats to three dose levels of 2,3,7,8-TCDD. Reproductive LOAELs and NOAELs were 0.00001 and 0.000001 mg/kg bw/d, respectively. From these results, Sample et al. (1996) derived red fox and short-tailed shrew LOAELs (normalized to body weight) of 0.0000053 and 0.000022 mg/kg bw/d, respectively, and NOAELs of 0.0000005 and 0.0000022 mg/kg bw/d, respectively. Poiger et al. (1989, reviewed in Sample et al., 1996) dosed laboratory rats with 1,2,3,7,8-PeCDF, 2,3,4,7,8- PeCDF, 1,2,3,4,8-PeCDF, and 1,2,3,6,7,8-HxCDF over a 13-week time period. However, these studies did not focus on effects on reproduction and are, therefore, not used to select TRVs in this ERA. Sample, B.E., D.M. Opresko, and G.W. Suter. 1996. Toxicological benchmarks for wildlife: 1996 revision. Department of Energy, Oak Ridge, TN. The discussion of mammalian studies presented in sections 5.3.2 and 5.3.3 is inaccurate, biased, and incomplete. These and other areas of the document discussing mammalian studies will require revision. The Murray et al (1979) three-generation rat study, evaluated by EPA in three separate documents, has generally considered the lowest dose (1.0 ng/kg) to be a NOAEL, although it was acknowledged that potential adverse effects could have occurred at that lowest dose (EPA 1985, 1987, 1995). In discussing the Murray study, the SRI included arguments taken directly from "*Do Not Quote or Cite*" EPA documents that were never finalized and were originally based upon the opinion of one scientist (Kimmel 1988; EPA 2010). In accordance with EPA policies, the 1988 and 2010 EPA citations of these drafts will need to be removed from the SRI document. The SRI includes factually erroneous conclusions (e.g., Section 5.3.3, 3rd paragraph), shown below, that must be removed from all locations in the document before approval. *"Because the Murray et al. (1979) reproductive endpoints are over an order of magnitude lower than reproductive effect levels observed in all the other studies reviewed, use of this NOAEL TRV selected for mammals may overstate toxicity because it is not bounded by other studies and is an artifact of the doses selected for testing (i.e., 1 and 10 ng/kg BW/day). The actual NOAEL could be much higher than the value selected. In addition, given the fact that the NOAEL TRV is more than an order of magnitude below the lowest values from the remaining body of literature, it is likely that this value is conservative and would overestimate potential for adverse effects."* The body of literature clearly demonstrates that the Murray three-generation reproductive study is fully supported by studies showing lower LOAELs. The Murray study is not conservative and does not overestimate the potential for adverse effects. Therefore, the following studies and language, as written, needs to be included the SRI, replacing the removed text. *Latchoumycandane and Mathur (2002) conducted a sub-chronic study to determine whether treatment with vitamin E protected rat testes from TCDD-induced oxidative stress. Groups of male rats were administered an oral dose of 0, 1.0, 10, or 100 ng TCDD/kg-day for 45 days, while another group of animals was co-administered TCDD at the same doses, along with vitamin E at 20 mg/kg-day. The 1.0 ng TCDD dose is the same as lowest low dose used in the Murray three generation rat study. Testis, epididymis, seminal vesicle, and ventral prostate weights in the TCDD-treated groups decreased significantly ($p < 0.05$) and sperm production also decreased significantly ($p < 0.05$) in a dose related response when compared to controls. None of these changes were observed in the TCDD-exposed groups receiving vitamin E. A LOAEL of 1.0 ng/kg-day was found for reduced sperm and decreased reproductive organ weights ($p < 0.05$). A NOAEL could not be determined for this study.* *Shi et al. (2007) administered pregnant rats oral doses of 0, 1, 5, 50, or 200 ng/kg TCDD on gestational days 14 and 21 and on post-natal days 7 and 14 for lactational exposure to pups. Ten female pups per treatment were selected and administered TCDD weekly at the same dose levels through their reproductive lifespan (approximately 11 months). The corresponding equivalent daily TCDD doses were 0, 0.14,*

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				0.71, 7.14, and 28.6 ng/kg-day. Serum estradiol concentrations were decreased at all time points across the estrous cycle in a dose-dependent manner with a statistically significant decrease ($p < 0.05$) in all but 0.14 ng/day group. TCDD exposure, however, did not affect ovarian follicles; responsiveness of the pituitary gland to gonadotropin-releasing hormone, or serum profiles of FSH, LH, or progesterone. A LOAEL for TCDD of 0.71 ng/kg-day for an 11-month exposure duration was identified in this study based on significantly ($p < 0.05$) decreased estradiol levels in offspring. The NOAEL for the study was found to be 0.14 ng/kg-day. In Section 4, two teratogenic studies are cited (Courtney et al, 1970 [listed in the references as Courtney and Moore, 1971]; and Couture et al., 1989) in support of the Sparschu gestational 10-day acute study. Courtney and Moore was also a 10-day a gestational exposure study and must be cited as a 10-day, short-term study. Based upon the previous discussion of the Sparschu study, the Courtney and Moore study has no relevance in determining LOAELs/NOAELs and RBCs for TCDD. The Couture study is based upon 2,3,4,7,8-PCDF, which has significantly lower toxicity (TEF=0.3) than 2,3,7,8-TCDD. As discussed by Sample et al. (1996) and Galbraith (2004) it must not be considered in TRV development or in selecting site RBCs. If AMEC/GP choses to maintain the citation, then the conclusions from both the Sample and Galbraith analyses will need to be included in a revised document. Regardless, both the Sample and Galbraith analyses need to be cited and discussed in the SRI. Courtney, K. and J Moore. 1971. Teratology studies with 2,4,5-trichlorophenoxyacetic acid and 2,3,7,8-tetrachloro-dibenzo-p-dioxin. *Toxicol. Appl. Pharmacol*. 20: 396–403. Couture, et al. 1989. Developmental Toxicity of 2,3,4,7,8-Pentachlorodibenzo furan in Fisher 344 Rat. *Fund. Appl. Toxicol*. 12: 358-366. Latchoumycandane, C. and Mathur, P. Effects of vitamin E on reactive oxygen species-mediated 2,3,7,8-tetrachlorodibenzo-p-dioxin toxicity in rat testis, *Journal of Applied Toxicology*, 22, pg. 345-351, 2002. Murray, et al., Three generation reproduction study off rats given 2,3,7,8- Tetrachlorodibenzo-p-dioxin (TCDD) in the diet, *Toxicology and Applied Pharmacology*, Vol. 50 (2), pgs. 241-252, 1979. Sample, B.E., D.M. Opresko, and G.W. Suter. 1996. Toxicological benchmarks for wildlife: 1996 revision. Department of Energy, Oak Ridge, TN. Sparschu, et al., Study of the teratogenicity of 2,3,7,8-Tetrachlorodibenzo-p-dioxin in the rat, *Food and Cosmetic Tox.* 9(3), pg., 405-412, 1971. Galbraith Environmental Services. 2004. Tittabawassee river floodplain screening-level ecological risk assessment: Polychlorinated dibenzo-*p*-dioxins and polychlorinated dibenzofurans, Submitted to: Michigan department of environmental quality, Galbraith Environmental Sciences LLC, April 2004. http://www.michigan.gov/documents/deq/deq-whm-hwp-dow-TR-FloodplainReport_251817_7.PDF EPA. 1987. 2,3,7,8-Tetrachlorodibenzo-p-dioxin, Health Advisory, Office of Drinking Water, March 31, 1987. EPA. 1985. Health Assessment for Polychlorinated Dibenzo-p-dioxins, EPA/600/8-84/014F, September 1985. EPA. 1995. Great Lakes Water Quality Initiative Criteria Documents for the Protection of Wildlife: DDT, Mercury, 2,3,7,8-TCDD, PCBs. EPA-820-B-95-0083. Appropriate discussion of Murray et al. and Sparschu et al. must be included in all sections where TRVs are considered.

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75.	L6-49 L6-50 L6-72	Appendix L, Section 6.4.4.5.3 & Figure L6-10 Appendix L, Section 6.4.4.5.4 Appendix L, Section 6.5.2.4 & Figure L6-12		The LOAEL TRV derived for birds (derived from an injected does of 140 ppt/d) killed more than half of the exposed birds in the cited study. Yet the TBERA derives an avian RBC range that reflects doses up to 500 times higher than the avian acute LD . The LOAEL TRV for mammals showed significant mortality at 100 ppt. Yet the TBERA derives a mammalian RBC range that reflects doses up to 750 times that exposure. These very large differences in RBCs reported from other sites, including the Tittabawassee River, and the literature need thorough explanation which takes into account the difficulties with TRV evaluation noted in previous comments. RBCs that indicate that exposed receptors will receive lethal doses cannot be used to define RBC useful for risk management.
76.	L6-71	Appendix L, Section 6.5.2.4		The section is titled, "Weight of Evidence for Carnivorous Birds and Mammals", but there were no carnivorous birds included in the TBERA. There was one carnivorous mammal, the red fox, but the fox is not mentioned in this section and the WOE results for the fox are not summarized. Additionally, the shrew (a vermivorous mammal) is discussed in this section. Revise the section to include the fox and delete the mentions of birds and shrews.
77.	L7-1	Appendix L, Section 7	First paragraph	The TBERA risk summary states that unacceptable risk is not anticipated based on LOAEL-based risk estimates. However, according to EPA's ERAGS, the LOAEL-based risk estimates are by definition the contaminant concentrations at which adverse impacts are likely. The TBERA ignores the NOAEL-based risk estimates, but the NOAEL-based estimates should be primary endpoints used to assess risk, as noted in the comments above. This section will also require revision to reflect the corrected HQ and RBC calculations discussed in the following comment, along with the corrected earthworm BSAFs, the appropriate TRVs for bioaccumulative compounds, and the revised RBCs.
78.	L7-1	Appendix L, Section 7, 1st paragraph		The TBERA risk summary states that unacceptable risk is not anticipated based on LOAEL-based risk estimates. However, according to EPA's ERAGS, the LOAEL-based risk estimates are by definition the contaminant concentrations at which adverse impacts are likely. The TBERA ignores the NOAEL-based risk estimates, but the NOAEL-based estimates should be the primary endpoints used to assess risk.